

2/26/99

K 982663

510(k) Summary

Submitter's Name: Encore Orthopedics, Inc.
Submitter's Address: 9800 Metric Blvd., Austin, TX 78758
Submitter's Telephone Number: (512) 834-6237
Contact Person: Debbie De Los Santos
Submission Date: July 30, 1998
Trade Name: Stimulan™ Calcium Sulfate Bone Void Filler
Common Name: Calcium Sulfate
Classification Name: Unknown
Legally Marketed Predicate Device: Wright Medical – Osteoset Pellets
BioGeneration – ProFusion Bone Graft Substitute

Device Description:

Stimulan™ Calcium Sulfate Bone Void Filler pellets are provided sterile for single patient use. The biodegradable, radiopaque pellets are resorbed in approximately 30-60 days when used in accordance with the device labeling. Stimulan™ is manufactured from 98% medical grade calcium sulfate dihydrate ($\text{CaSO}_4 - 2\text{H}_2\text{O}$) and stearic acid.

Indications For Use:

Stimulan™ is intended for use in clinical situations where the use of autologous grafts or other bone graft substitutes may be undesirable, due either to the risk of associated infection or unavailability. Stimulan™ is manufactured from medical grade calcium sulfate that resorbs and is replaced with bone during the healing process. Also, as the implant is biodegradable and biocompatible, it may be used at an infected site.

Technological Characteristics:

Stimulan™ has the equivalent technological characteristics (i.e. chemical composition, and dissolution rate performance as the predicate device.

Performance Data:

Testing demonstrated that Stimulan™ has equivalent dissolution, mechanical and mass to volume ratio characteristics to the predicate device. Testing indicated that the product is non-pyrogenic.

Basis for Substantial Equivalence:

Stimulan™ is safe and effective because it is equivalent to the predicate device in terms of chemical composition, indication of use, and product performances.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 1999

Ms. Debbie De Los Santos
Regulatory/Clinical Specialist
Encore Orthopedics
9800 Metric Boulevard
Austin, Texas 78758

Re: K982663
Trade Name: Stimulan™ - Calcium Sulfate Bone Void Filler
Regulatory Class: Unclassified
Product Code: MQV
Dated: January 29, 1999
Received: February 5, 1999

Dear Ms. De Los Santos:

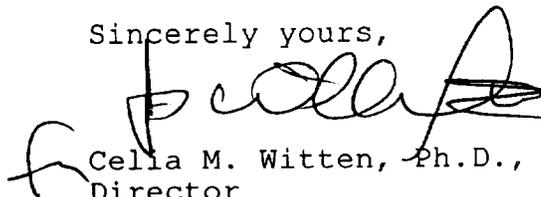
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Cella M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Stimulan™

Indications For Use:

Stimulan™

Indications For Use

Stimulan™ is intended for use in clinical situations where the use of autologous grafts or other bone graft substitutes may be undesirable, due either to the risk of associated infection or unavailability. Stimulan™ is manufactured from medical grade calcium sulfate that resorbs and is replaced with bone during the healing process. Also, as the implant is biodegradable and biocompatible, it may be used at an infected site.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

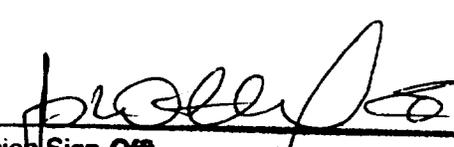
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)_



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 1982663